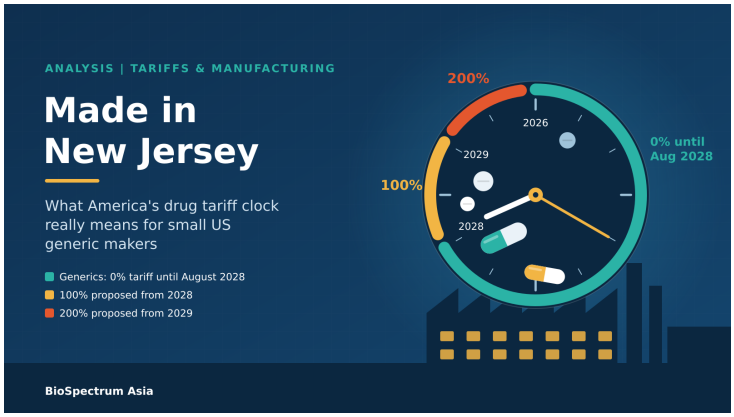
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Made in New Jersey: What America's Drug Tariff Clock Really Means for Small US Generic Makers

November 14, 2026 | Analysis | By Ankit Kankar | ankit.kankar@mmactiv.com

Washington's tariff campaign has made "made in the USA" the hottest phrase in pharma investing. Elite Pharmaceuticals shows where that phrase creates real value, and where the excitement runs ahead of the rules.



100%
Default US tariff on imported patented drugs since 2026

0%
Tariff on imported generics until Aug 2028

200%
Proposed generic tariff from 2029

$40.1M
Elite's Q2 FY2027 rev

At a glance

- **The tariff most people quote is the wrong one.** The branded drug tariff does not apply to generics or to drugs made in the U not a fix for it, and not directly affected by it.
- **The generic clock is what counts.** Imported generics are tariff-free until August 2028, with 100% and then 200% duties propo that. That is the clock that matters for US generic plants.
- **Elite is profitable but concentrated.** Revenue is growing, debt is low and cash is building. About 80% of sales still come from drugs.
- **2028 is the pivotal year.** A generic for a drug with roughly $26 billion in brand sales is aimed at a 2028 launch, the same year import tariffs are due to start.
- **Execution risk is real.** FDA and patent timelines, DEA quotas, a single-shift plant, warrant dilution and a Nasdaq process still

Every tariff cycle produces a new favourite trade. In 2026, it is the small American drugmaker with a factory on home soil. Investors who once ignored domestic generic plants are now scanning OTC listings for anything with a US address and an FDA approval. Elite Pharmaceuticals, a profitable generic manufacturer in Northvale, New Jersey, has become one of the names in circulation.

It deserves a careful look. Not because Elite is the answer to America's drug tariff problem, but because it is a clean case study of how the new rules actually work, who they reward, and how long the rewards take to arrive.

1. First, get the tariff right

The headline figure is not 80%. Under Proclamation 11020, signed on 2 April 2026, Washington set a default tariff of up to 100% on imported branded drugs, with relief for manufacturers that agree to move production to the US or sign pricing deals. The duties took effect on 31 July 2026 for 17 named companies and on 29 September 2026 for everyone else.

Two exemptions sit at the heart of this story. Generic drugs and biosimilars are outside the tariff, and so are drugs made in the US. The branded tariff, in other words, is solved by branded companies building American plants or signing pricing deals. A domestic generic maker is neither taxed nor protected by it.

The clock that actually matters

The policy that bears on companies like Elite came in July. President Trump said imported generics would carry no tariff for two years from 1 August 2026, followed by 100% in 2028 and 200% in 2029, describing the eventual duty as a penalty for companies that do not build US capacity in time. It was announced on social media rather than in a proclamation, so details can still change. Industry groups see it as an opening position for negotiation, much like the deals branded drugmakers struck to win exemptions.

The stakes are large. Generics make up about 90% of US prescriptions but only a fraction of drug spending, and India supplies 47% of US generic prescriptions. A genuine tariff on that flow would reshape the market.

Date	Branded / patented drugs	Generic drugs
2 Apr 2026	Proclamation 11020 signed: up to 100%	Exempt
31 Jul 2026	Duties start for 17 named companies	Exempt
1 Aug 2026		Two-year 0% transition begins (announce
29 Sep 2026	Duties apply to all other importers	Exempt
Aug 2028	Unchanged	100% tariff proposed
2029	Unchanged	200% tariff proposed

2. Why a small New Jersey plant is getting attention

Elite develops, manufactures and sells niche oral generics from a DEA-registered facility, with a strong position in controlled substances. Its core franchise is ADHD: generic Vyvanse (lisdexamfetamine) and generic Adderall IR and XR

together account for about 80% of revenue, according to management. The quarter to 30 September 2026, reported on 13 November, showed steady growth:

Metric	Q2 FY2027 (Jul to Sep 2026)	Comparison
Revenue	$40.1 million	$36.3 million a year earlier (+10%
Gross profit	$16 million (40% margin)	$14 million (39%) a year earlier
R&D expense	$1.9 million	$1.4 million a year earlier (+35%)
Cash	$35 million	$30 million at 31 Mar 2026
Working capital	$103 million	$95 million at 31 Mar 2026
Liabilities excl. warrant derivatives	$14.5 million	$22.1 million at 31 Mar 2026 (-34

Source: Elite Pharmaceuticals Q2 FY2027 earnings call, 13 November 2026.

The quality of revenue has improved. A year ago, a $40 million quarter rested on early, high-priced generic Vyvanse sales. This year's $40 million is spread across amphetamines, opioid addiction treatment and a growing set of non-controlled products such as ropinirole, which pushed that segment from $4.3 million to $5.9 million in a quarter. The price of maturity shows in margins: gross margin is now near 40%, down from 54% a year earlier, as generic Vyvanse pricing corrected. Management says that market is now stabilising and volumes are rising.

3. The pipeline is the real story, and it points to 2028

Investors chasing the tariff angle often miss that Elite's most valuable products have not launched yet.

Programme	Opportunity	Stated timing
Anticoagulant (undisclosed)	Brand sales of about $26 billion (IQVIA, 12 months to Mar 2026)	FDA goal date Mar 2027; launch subject to agreement with brand
Second anticoagulant	Advanced development	BE study H1 2027; approval hope
Anticonvulsant (undisclosed)	Brand sales of about $840 million	ANDA filing Q1 2027
Type 2 diabetes portfolio	Now four formulations	First BE study H1 2027
Oxycodone ER (generic OxyContin)	Opioid franchise extension	Under FDA review

“2027 is going to be the year of R&D and 2028 is the year of the second growth.”
Nasrat Hakim, Chairman and CEO, Elite Pharmaceuticals, 13 November 2026

There is a neat, if accidental, alignment here. Elite's biggest launch window and the proposed start of tariffs on imported generics both land in 2028. But a caveat matters: these are generic versions of drugs still under patent. They will be generics when they launch, so the branded tariff never touches them. Their value depends on FDA approval and patent agreements, not on trade policy.

4. How Elite fits the wider onshoring race

Elite is a small player in a much bigger shift. Generic makers, long considered too low-margin to reshore, have started to commit capital:

Company	US move	Type
Hikma	$1 billion by 2030 to expand US manufacturing and R&D in Ohio and New Jersey	Expansion
Aurobindo Pharma	$250 million Lannett acquisition, adding an Indiana plant with about 4 billion doses of annual capacity	Acquisition
Amneal	Completed Kashiv BioSciences acquisition: two New Jersey facilities over 150,000 sq ft plus a Chicago site	Acquisition
Lupin	$250 million new manufacturing facility in Florida	New build
Elite Pharmaceuticals	Growing from about 85,000 to 130,000 sq ft of GMP space in Northvale, NJ	Expansion

The pattern is telling. Building from scratch is slow: a new plant would likely take at least three years to go live, longer than the tariff runway. That makes existing, approved, licensed US plants the scarce asset, and it explains why acquisitions are leading the response. As one industry analysis put it, the policy rewards usable domestic capacity more than corporate scale.

5. Strengths and risks, side by side

Where onshoring genuinely helps	Where the story runs ahead of the facts
Domestic capacity becomes scarce and valuable if generic duties arrive in 2028.	The generic tariff is an announcement, not yet a proclamati could be negotiated away.
A DEA-registered plant gives Elite a moat in controlled substances that has nothing to do with tariffs.	DEA quota, not demand, is the main brake on generic Vyva growth, per management.

Where onshoring genuinely helps	Where the story runs ahead of the facts
A buyer made a verbal offer about three weeks before the call, a sign of strategic interest.	The board rejected that offer and shelved talks until 2027. T M&A news is a no, not a deal.
Low debt, $35 million cash and $103 million working capital fund R&D and expansion internally.	Warrants for about 79 million shares expire in April 2027, a overhang.
Facility growth to about 130,000 sq ft of GMP space.	The plant runs one shift, and the new building may not proc commercially until 2028.
Revenue is more diversified than a year ago.	About 80% of revenue is still in one therapeutic family.
Pipeline targets multi-billion-dollar brands.	Reported material weakness in internal controls; an indepe controls audit is due in fiscal 2028.

The API question

A US-made tablet is not necessarily US-made all the way down. Many domestic generic plants rely on imported active ingredients. If future generic tariffs reach APIs and starting materials, input costs could rise even for American factories, eroding the advantage onshoring is supposed to create. Elite has not detailed its API sourcing mix, and it is the single most useful question an investor or partner can put to management.

6. The Asia angle

For readers in India and across Asia, the tariff clock cuts both ways. Generic exporters typically earn margins of just 10 to 15%, which cannot absorb a 100% or 200% duty. Lupin earns 42% of its revenue in the US and Dr Reddy's 34%, so exposure is concentrated. Yet building is slow and expensive: Dr Reddy's CEO estimates moving operations to the US would take four to seven years, and generics cost about 30 to 50% less to make in India.

That leaves three realistic routes for Asian manufacturers inside the two-year window: buy approved US capacity, partner with domestic manufacturers, or shift the US portfolio toward complex generics, injectables and biosimilars that can carry higher costs. Small, profitable American plants with DEA licences and clean FDA records fit the first two routes precisely. That, more than any single product, is why companies like Elite are suddenly on more radar screens in Mumbai, Hyderabad and beyond.

India's industry is also lobbying. The Indian Pharmaceutical Alliance has pointed out that its members already run more than 40 US facilities, and has asked for engagement with Washington. Whether US-based subsidiaries of Asian firms receive flexibility will be one of the most important policy details of 2027.

7. Five questions to ask before backing any US generic onshoring story

1. **Policy certainty.** Is the advantage tied to an announced policy or a signed proclamation?
2. **Input exposure.** Where do the APIs and starting materials come from, and would they be tariffed?
3. **Real capacity.** How much approved, staffed, multi-shift capacity exists today, not in 2028?
4. Do launches depend on patent agreements, DEA quotas or FDA dates outside the company's control?
5. **Capital structure.** What are the dilution, governance and listing hurdles over the next 12 months?

8. What to watch over the next six months

Milestone	What to look for
Jan to Feb 2027	Shareholder meeting to elect two new directors, a Nasdaq prerequisite
Q1 2027	Nasdaq application and anticonvulsant ANDA filing
Mar 2027	FDA goal date on the anticoagulant; management targets a Nasdaq listing the same mon
Apr 2027	Warrant expiry: cash exercise would raise about $12 million but add up to 79 million shar
H1 2027	First diabetes and second anticoagulant bioequivalence studies
Ongoing	Whether the 2028 generic tariff is formalised in a proclamation

Reading the clock

Elite is a real business with growing revenue, cash in the bank and very little debt, which is rare among small generic makers. But its value rests on execution: FDA approvals, patent agreements, DEA quotas and a facility build-out, most of it landing in 2027 and 2028. The tariff regime may add a tailwind if generic duties arrive as announced, and it is already making domestic capacity a strategic asset worth buying.

For investors, partners and Asian manufacturers alike, the lesson is the same. Onshoring is a clock, not a cure. The winners will be the companies that can show approved capacity, secure inputs and a pipeline that pays off whatever Washington decides next.

Disclosure: This analysis draws on Elite Pharmaceuticals' 13 November 2026 earnings call, company press releases, public tariff documents and industry reporting. It is for information only and is not investment advice. Company forward-looking statements are subject to risks described in its SEC filings.